

S/N. unknown

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: SHAPIRO et al. Serial No.: unknown  
Filed: concurrent herewith Docket No.: 9124.103USC1  
Title: POLYSACCHARIDE SPONGES FOR CELL CULTURE AND  
TRANSPLANTATION

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By:   
Name: Chris Stordahl

PRELIMINARY AMENDMENT

Box PCT  
Assistant Commissioner for Patents  
Washington, D. C. 20231

Dear Sir:

In connection with the above-identified application filed herewith, please enter the following preliminary amendment, which is based on the Article 14 amendments, and published in the International Preliminary Examination Report, a copy of which is enclosed herewith:

IN THE ABSTRACT

Insert the attached Abstract page into the application as the last page thereof.

IN THE SPECIFICATION

Please enter the specification as amended during prosecution of the international application PCT//IL97/00161 and published in the International Preliminary Examination Report for that application, a copy of which is included herewith.

IN THE CLAIMS

Please amend claims 7 and 9-10, 14 and 39 as follows:

7. (Amended) A polysaccharide sponge according to claim 1, wherein said sponge further comprises a cross-linking agent selected from the group consisting of the salts of calcium,

copper, aluminum, magnesium, strontium, barium, tin, zinc, chromium, organic cations,

poly(amino acids), poly(ethyleneimine), poly(vinylamine), poly(allylamine), and

polysaccharides.

9. (Amended) A polysaccharide sponge according to claim 7, wherein said cross-linker is

used in the form of a cross-linker solution having a concentration of cross-linker sufficient to

provide a cross-linker concentration between about 0.1% to about 0.3% w/v in the final solution

from which the sponge is obtained.

10. (Amended) A polysaccharide sponge according to claim 1, wherein said sponge is

prepared from a polysaccharide solution with or without the addition of a cross-linker.

14. (Amended) A polysaccharide sponge according to claim 1 for use as a matrix, substrate or scaffold for growing mammalian cells *in vitro*.

39. (Amended) An artificial organ equivalent comprising a polysaccharide sponge according to claim 1 and representative cells of said organ, said cells having been grown on said sponge *in vitro* to the stage wherein said cells are fully active and equivalent to the active cells of said organ, said artificial organ being suitable for transplantation or implantation into a patient in need thereof following organ damage, removal or dysfunction.

REMARKS

The above preliminary amendment is made to include amendments to the international application PCT/IL97/00161, published in the International Preliminary Examination Report for that application and to remove multiple dependencies from claims 7, 9-10, 14 and 39.

A new abstract page is supplied to conform to that appearing on the publication page of the WIPO application, but the new Abstract is typed on a separate page as required by U.S. practice.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Marked-up Copy".

Applicants respectfully request that the preliminary amendment described herein be entered into the record prior to calculation of the filing fee and prior to examination and consideration of the above-identified application.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' primary attorney-of record, Gregory A. Sebald (Reg. No. 3,280), at (612) 336.4728.

Respectfully submitted,

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Dated: 23 October 2001  
By   
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GAS:hjh

## ABSTRACT

A polysaccharide sponge characterized by having: (i) an average pore size in the range between about 10  $\mu\text{m}$  to about 300  $\mu\text{m}$ ; (ii) an average distance between the pores being the wall thickness of the pores in the range between about 5  $\mu\text{m}$  to about 270  $\mu\text{m}$ ; and (iii) an E-modulus of elasticity being a measure of the rigidity of the sponge in the range of about 50 kPa to about 500kPa.

**MARKED-UP COPY**

7. A polysaccharide sponge according to [any one of claims 1 to 5,] claim 1, wherein said sponge further comprises a cross-linking agent selected from the group consisting of the salts of calcium, copper, aluminum, magnesium, strontium, barium, tin, zinc, chromium, organic cations, poly(amino acids), poly(ethyleneimine), poly(vinylamine), poly(allylamine), and polysaccharides.

9. A polysaccharide sponge according to claim 7 [or claim 8], wherein said cross-linker is used in the form of a cross-linker solution having a concentration of cross-linker sufficient to provide a cross-linker concentration between about 0.1% to about 0.3% w/v in the final solution from which the sponge is obtained.

10. A polysaccharide sponge according to [any one of claims 1 to 9,] claim 1, wherein said sponge is prepared from a polysaccharide solution with or without the addition of a cross-linker.

14. A polysaccharide sponge according to [any one of claims 1 to 13] claim 1 for use as a matrix, substrate or scaffold for growing mammalian cells in vitro.

39. An artificial organ equivalent comprising a polysaccharide sponge according to [any one of claims 1 to 13] claim 1 and representative cells of said organ, said cells having been grown on said sponge *in vitro* to the stage wherein said cells are fully active and equivalent to the active cells of said organ, said artificial organ being suitable for transplantation or implantation into a patient in need thereof following organ damage, removal or dysfunction.